DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 26 1999

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Mr. Stephen J. Graham
10 Howard Court
Woburn, Massachusetts 01801-5805

Dear Mr. Graham:

Thank you for your correspondence to Senator Edward M. Kennedy, regarding proposed new Food and Drug Administration (FDA or the Agency) regulations on statements made for dietary supplements concerning the effect of the product on the structure or function of the body. Senator Kennedy has asked us to respond directly to you.

FDA published this proposed rule in the Federal Register on April 29, 1998. The comment period closed on August 27, 1998; however, FDA extended the comment period until September 28, 1998. FDA invited written comments on the proposal from the public and industry. All comments received will be reviewed and considered by the Agency in developing the final rule.

Your comments have been forwarded to the docket for this issue. While the Agency is under no legal obligation to consider comments received after the comment period, we do try to accommodate all comments as time and resources permit.

Enclosed is information which may be of interest to you. We hope this information has been helpful.

Sincerely,

Timothy P. Tynan

for Melinda K. Plaisier
Interim Associate Commissioner
for Legislative Affairs

Enclosure
April 24, 1998 HHS News release

cc: Dockets Management Branch
(Docket No. 98N-0044)

The Honorable Edward M. Kennedy
United States Senator
2400A John F. Kennedy Federal Building
Government Center
Boston, Massachusetts 02203

98N-0044

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Washington D.C. 20201 – 0001

MAR 2 1999

Executive Secretariat Office
Food and Drug Administration
Fishers Lane Room 1670
Rockville, Maryland 20857

Dear Ms. Clarke:

The attached correspondence was received by the Health Care Financing Administration. Since it appears that the attached correspondence can best be evaluated by your office, we are referring correspondence to you for your consideration and appropriate action.

Sincerely,

Deborah Miller for

Mary Ann Troanovitch
Director
Division of Correspondence
Control and Management

Enclosures

No 99-1517

August 7, 1998

United States Senate

MEMORANDUM

Respectfully referred to:

Ms. Diane Thomson
Associate Comm. for Legislative Affairs
FDA
Dept. of HHS

My assistance has been requested concerning the attached correspondence.

I am forwarding this to you for your attention and consideration, and would appreciate your prompt reply directly to the constituent, with a copy sent to me at:

2400A John F. Kennedy Federal Bldg.
Government Center
Boston, Massachusetts 02203

Thank you for your attention and consideration.

Sincerely,

Edward M. Kennedy
United States Senator

For additional information, please contact _____ at (617) 565-3170

No 99-1517

CITIZENS PETITION

TO: FDA- Dockets Management Branch (HFA-305)
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

RE: [Docket No. 98N-0044] RIN 0910-AA59 Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Proposed Rule and Dietary Supplements: Comments on Report of the Commission on Dietary Supplement Labels; Notice

Please be advised that I vehemently oppose the proposed restrictions on the dissemination of medical information as it relates to dietary supplement health claims for the following reasons:

1. I need this information to determine what supplements I should take and which supplements I should avoid. Your restriction on the types of claims that can be made will adversely effect my health, and the health of the millions of Americans who rely on the dissemination of specific medical information relating to disease states in order to determine which dietary supplements to take.

2. Your proposed rules are in violation of the free speech provisions enumerated in the First Amendment to the United States Constitution.

3. Your proposed rules are contrary to a Supreme Court decision on June 28, 1993. The Commission on Dietary Supplement Labels (whose advice you were following when you drafted your proposed rule) defied the Supreme Court Decision of Daubert v. Merrill Dow. (I hereby put you on notice that the FDA is required to abide by Supreme Court decisions when proposing new regulations.)

4. In your proposed rule, you say that it would be illegal to suggest anything but drugs to reduce nausea associated with chemotherapy. This is arbitrary and capricious. What about nutrients such as ginger that have been shown to reduce nausea? What about coenzyme Q10 and vitamin E to reduce chemotherapy-induced cardiomyopathies, melatonin to reduce chemotherapy-induced immune system damage, and N-acetylcysteine to reduce chemotherapy induced liver damage? Are cancer patients to be denied this information?

Because your proposed rule is of questionable legality in view of the Daubert decision, and will cause many Americans to suffer and die, I hereby call for its immediate withdrawal.

Signed: Stephen J. Graham Date: 8-5-98

Address: 10 Howard Court

City/State/Zip: Woburn MA 01801-5805

CC: To my U.S. representative and two senators